NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TYCO HEALTHCARE GROUP LP and MALLINCKRODT INC., Plaintiffs, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC., Defendants.	Civil Action No. 07-1299 (SRC) **OPINION**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion by Plaintiffs Tyco Healthcare Group LP and Mallinckrodt Inc. (collectively, "Tyco") for a preliminary injunction, pursuant to FED. R. CIV. P. 65, enjoining Defendants Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively, "Mutual") from marketing or selling a generic 7.5 mg temazepam product. For the reasons stated below, Ortho's motion for a preliminary injunction is **DENIED**.

BACKGROUND

This case arises out of an action for patent infringement. Briefly, Mallinkrodt Inc. owns U.S. Patent No. 5,211,954 (the "'954 patent"), which is directed to a low-dose temazepam composition. The '954 patent was issued on May 18, 1993, and it will expire on May 18, 2010. Tyco Healthcare Group LP holds an FDA-approved supplement to new drug application No. 18-163 for Restoril® temazepam capsules. On November 1, 2006, Mutual filed ANDA No. 78-581,

seeking approval from the FDA to engage in the manufacture and sale of certain temazepam products. On March 20, 2007, Plaintiffs responded with this infringement action. Plaintiffs originally asserted infringement of four patents, but three of those patents have since expired, leaving only the '954 patent at issue.

In July of 2008, Tyco began selling an unbranded 7.5 mg temazepam product. (McBean Decl. ¶ 12.)

The 30-month stay of FDA approval of Mutual's ANDA expires on August 12, 2009. Mutual intends to launch its generic temazepam product once the 30-month stay expires and Mutual receives final FDA approval. On July 16, 2009, this Court denied Tyco's motion for an extension of the 30-month stay. On July 14, 2009, Tyco filed the instant motion for a preliminary injunction, seeking to prevent Mutual from launching its generic product when the 30-month stay expires.

In this motion, Tyco asserts only claim 2 of the '954 patent, which states:

> A hard gelatin capsule containing a temazepam formulation consisting essentially of 7.5 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m.sup.2 /g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.

'954 Patent col. 4 ll.7 - 12. The parties agree that the phrase "surface area" in claim 2 should be construed to mean "specific surface area" ("SSA"), as it is generally understood in the art.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed.

Cir. 2006). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008).

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

> [T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation omitted).

II. Infringement

The test for patent infringement requires a two step analysis: "the claim scope is first determined, and then the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350-1351 (Fed. Cir. 2001). "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005) (internal citations omitted). Although claim construction is an issue of law, the determination of infringement is a question of fact. Pause Tech. LLC v.

TiVo Inc., 419 F.3d 1326, 1329 (Fed. Cir. 2005).

ANALYSIS

I. Plaintiff has not demonstrated that it is likely to succeed on the merits.

To show that it is likely to succeed on the merits, Tyco must demonstrate that it will likely prove infringement of claim 2, and that it will likely withstand Mutual's challenge to the validity of the patent. Tyco has failed to show that it is likely to prove literal infringement pursuant to 35 U.S.C. § 271(e)(2)(A).[1]

At issue is whether Tyco's infringement case must fail under the holding of Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000). In Elan, the accused infringer had submitted an ANDA which stated a specific surface area for the pharmaceutical product which did not literally infringe the patent at issue. Id. The trial court had entered summary judgment of no infringement, and the Federal Circuit affirmed, analyzing the question of infringement using these principles:

> The focus, under § 271(e)(2)(A), is on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred. This hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support. Therefore, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder. However, if the ANDA is to sell [a] well-defined compound, then the ultimate question of infringement is usually straightforward.

Id. at 1248-49 (citations omitted). The Federal Circuit looked to the surface area specification in the ANDA and found that a product manufactured to that specification could not literally infringe the patent. Id. at 1249. Furthermore, the Court rejected the patentee's infringement argument

[1] Tyco does not assert any claim for infringement under the doctrine of equivalents in bringing this motion. (Pl.'s Br. 17.)

based on the surface area measures of certain samples, holding that "the focus of the infringement inquiry under 35 U.S.C. § 271(e)(2)(A) is on the product that will be sold after the FDA's approval of the ANDA." Id. The Court observed the many penalties the accused infringer, Elan, would be subject to were it to market a product that did not conform to the ANDA, stating: "In short, the only drug Elan can produce upon approval of the ANDA at issue is a drug that does not literally infringe the [patent at issue]." Id. at 1250.

The Elan Court distinguished the decision in Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997), explaining that "the biobatch in *Glaxo* was properly considered because the ANDA specification in that case did not define the compound in a manner that directly addressed the issue of infringement." Elan, 212 F.3d at 1250. In applying the principles of Elan, then, the threshold question is whether the ANDA specification in this case defines the compound in a manner that directly addresses the issue of infringement.

Mutual offers the declaration and testimony of its expert, Dr. Robert Williams, who states that the ANDA specifies that the SSA of its temazepam is at least 2.2 square meters per gram. (Williams Decl. ¶ 4.) Tyco does not dispute this in its briefs, which are silent on the question of the ANDA SSA specification. Nor did Tyco present any evidence at the hearing to negate the conclusion that the ANDA specification in this case defines the compound in a manner that directly addresses the issue of infringement. Rather, Dr. Luk, Tyco's expert, admitted that it was possible to manufacture temazepam with a SSA that conformed to the ANDA and did not infringe the patent at issue.

On the present record, this Court concludes that, pursuant to its claim construction, the patent covers temazepam with a SSA below 1.1 square meters per gram and that the ANDA

specifies that the SSA of its temazepam is at least 2.2 square meters per gram. Based on these observations, this Court finds that the ANDA requires that Mutual market a temazepam product with a SSA that does not infringe the '954 patent. Pursuant to Elan, since Mutual cannot market an infringing product without subjecting itself to substantial penalties, this Court finds that Mutual has shown that "what the ANDA applicant will likely market if its application is approved" will not infringe. Elan, 212 F.3d at 1248.

Accordingly, this Court also finds that, following the analysis stated by the Federal Circuit in Elan, Tyco is not likely to prove, by a preponderance of the evidence, that the ANDA specifies a product that infringes. Tyco has therefore failed to demonstrate that it is likely to succeed on the merits of proving infringement.

This Court rejects Tyco's argument that Elan does not apply to the issues of infringement presently before the Court. Even if, however, this Court agreed that infringement should be determined based on the product samples rather than the ANDA, Tyco has not demonstrated that it is likely to succeed in proving infringement.

At the hearing, the parties offered testimony by their experts on the testing performed on a batch of Mutual's temazepam product known as the "Replacement Batch."[2] As evidence that Mutual's product samples infringe, Tyco points to the testing by its expert, Dr. Luk, and by Mutual's expert, Dr. Williams. Dr. Luk tested, with outgassing at 105ºC, a sample he obtained from Mutual on June 24, 2009 and made two SSA measurements of .97 and 1.00 square meters per gram. (Luk Decl. ¶¶ 25, 33.) Dr. Luk noted that Dr. Williams had performed a test with

[2] The parties did not present evidence as to tests on a previous batch of Mutual's product, which Mutual has now rejected.

outgassing at 105ºC and had obtained similar results. (Id. at ¶ 35.)

In response, Mutual offers the measurements by Particle Technology Labs ("PTL"), which tested four samples and obtained measurements in the range of 2.52 - 2.84 square meters per gram. (Williams Decl. ¶ 6.) Mutual argues that Dr. Luk's results are inaccurate, that Dr. Luk erred in his testing procedure by performing outgassing at 105ºC, and that this was a high temperature that altered the SSA. Dr. Williams states that outgassing of this compound should properly be performed at 40ºC. (Williams Decl. ¶ 13.)

In reply, Tyco concurs that this factual dispute turns on the question of which outgassing temperature should be used in the testing of Mutual's temazepam product. Indeed, at the hearing, the parties focused their examinations of the experts on this particular issue. In support of its assertion that the outgassing should be performed at 105ºC, Tyco offers three kinds of evidence: 1) the original patent owner (Sandoz) used an outgassing temperature of 105ºC; 2) a deposition statement by Dr. Williams; and 3) the expert testimony of Dr. Luk. Neither of the first two pieces of evidence deserves much weight. As to the method used by the original patent owner, Tyco does not explain how this is legally or factually relevant. During claim construction, this Court found that the SSA specifications in the claims were not limited to a particular SSA measurement method. How Sandoz measured SSA is of little help in resolving a dispute between two experts about the proper outgassing temperature.

As to the statement made by Dr. Williams at his deposition, Tyco quotes this exchange:

> Q: If I have a temazepam material and I wanted to determine whether its specific surface area falls within the patented range, the best conditions for me to use to answer that question would be to use the conditions that Sandoz used, correct?

A: If I, if I knew what Sandoz conditions were, that seems logical that one could use that.

(Pl.'s Reply Br. 3-4.) This exchange, on its face, simply does not support Tyco's assertion that Dr. Williams agreed that the SSA of Mutual's product could be adequately measured using an outgassing temperature of 105ºC. Nor was Tyco able to elicit testimony from Dr. Williams at the hearing that supported this assertion. Dr. Williams in no way conceded that it was appropriate to test the Mutual temazepam using outgassing at 105ºC.

At the hearing, Dr. Luk testified that the SSA test should be performed with outgassing at 105ºC, not 40ºC. In opposition, Dr. Williams testified that the SSA test should be performed with outgassing at 40ºC, not 105ºC. The parties appear not to dispute that the samples manifest an infringing SSA when tested with outgassing at 105ºC, but a noninfringing SSA when tested with outgassing at 40ºC.

Thus, were this Court to agree that the infringement analysis at this juncture should be based on product samples rather than ANDA specifications, this Court would have before it a factual dispute between experts on an obscure scientific point, the temperature at which outgassing should be conducted in a particular chemical analysis. Such a factual dispute would likely need to be resolved at trial by a battle of the experts. At the preliminary injunction hearing, this Court heard detailed testimony from each party's expert. Tyco's expert, Dr. Luk, did not persuasively articulate a basis for selecting 105ºC as the proper outgassing temperature. This Court observes that, according to Dr. Luk, Tyco never actually conducted any tests at 40ºC. Dr. Luk rejected Dr. Williams' tests at 40ºC solely because he viewed the variation in results as evidence of unreliability in the testing methodology. Dr. Williams, on the other hand, not only

tested Mutual's proposed product at a wide range of temperatures, but also tested the Sandoz temazepam product at the same range. (Williams 7/22/09 Decl. ¶ 18.) The results suggested to Dr. Williams that increasing the outgassing temperature had no significant effect on the measured surface area of the Sandoz temazepam, but caused a substantial decrease in the measured surface area of the Mutual temazepam. (Id.) This Court found Dr. Williams' opinion to be based on more comprehensive study and therefore more persuasive and deserving of greater weight.

Having heard the evidence at the preliminary injunction hearing, and having weighed it, this Court does not find Tyco's evidence sufficiently persuasive to conclude that Tyco is likely to prove infringement by a preponderance of the evidence at trial. To the contrary, this Court found that Mutual's expert raised substantial questions about the strength of Tyco's infringement case. Dr. Williams cited a number of bases for his conclusion that Tyco's SSA measurements were inaccurate because the outgassing temperature changed the SSA of the particles being tested. Dr. Williams' testimony also constitutes substantial evidence that Mutual's SSA measurement method gives accurate results.

Tyco's case for infringement, based on product samples – rather than the ANDA, pursuant to Elan – turns on being able to establish, by a preponderance of the evidence, that the SSA test should be performed with outgassing at 105ºC. Given the strength of Dr. Williams' testimony challenging Tyco's testing methodology, this Court cannot conclude that it is likely to do so. Mutual has raised a substantial question about Tyco's infringement case which Tyco has not shown lacks substantial merit. In conclusion, even if this Court were to look to the infringing nature of the product samples, as opposed to the product specified by the ANDA, it would

conclude that the injunction should not issue. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997) (when the accused infringer raises a substantial question about infringement which the patentee does not show lacks substantial merit, a preliminary injunction should not issue.)

On July 16, 2009, this Court heard oral argument on Tyco's motion to extend the 30-month stay. At the hearing, the Court heard argument on the question of if and how Elan applies to the present questions of infringement in this case. In the decision issued orally at that hearing, the Court held that Elan was controlling authority on the issue of infringement. Setting aside the question of whether this should constitute the law of the case, this gave Tyco notice of the salience of Elan in the Court's thinking about the issues of infringement in this case. The core holding of Elan is that, prior to FDA approval of the ANDA, the focus of the infringement question is "on what the ANDA applicant will likely market if its application is approved," and this inquiry is grounded in the ANDA application itself. Elan, 212 F.3d at 1248.

Under Elan, to show a likelihood of success on proving infringement, Tyco needed to show that it was likely to prove, by a preponderance of the evidence, either of these two propositions: 1) the ANDA specification in this case does not define the compound in a manner that directly addresses the issue of infringement, and the Court must look to other evidence to establish what the ANDA applicant will likely market if its application is approved; or 2) the ANDA specification in this case defines the compound in a manner that directly addresses the issue of infringement, and defines it as infringing. Tyco has not shown that it is likely to succeed on either track. Rather, Tyco argued that Elan was inapplicable, and Plaintiffs did not address, except in passing, the fundamental issue of whether the ANDA specification in this case defines

the compound in a manner that directly addresses the issue of infringement. At the conclusion of the hearing, in summing up the case, Tyco argued that the compound was not well-defined, within the meaning of Elan.[3] Yet Tyco failed to offer persuasive evidence to support this conclusion.

Mutual did offer evidence that the ANDA specification in this case defines the compound in a manner that directly addresses the issue of infringement, and that the temazepam product specified does not infringe. Tyco did not offer evidence to rebut this, and this Court thus finds that Tyco is not likely to succeed on the merits under Elan.

Tyco's main argument is that "Mutual's to-be-launched product, when tested properly, does not meet ANDA spec[ifications] for specific surface area." (Pl.'s Hrg. Summation at 6.) In relying predominantly on this argument, Tyco has overlooked the key inquiry that Elan requires. Thus, even if Tyco were to prove its main point, it would still fail to show that Tyco is likely to succeed in proving infringement under Elan. As this Court stated at the hearing, if, in fact, Mutual markets a temazepam product with a SSA that does not conform to the ANDA, it risks serious negative consequences with the FDA. On this record, this Court believes that the threat of such consequences will adequately protect Tyco's interests in the '954 patent.

Because this Court has concluded that Tyco has failed to demonstrate that it is likely to succeed on the merits of its infringement case, it need not reach any disputes over patent validity.

"[A] movant cannot be granted a preliminary injunction unless it establishes both of the

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[3] At the hearing, Tyco contended as well that Elan instructed the district court to consider all the evidence. While not strictly incorrect, this is a poor summary of the Federal Circuit's guidance in Elan. Elan makes clear that, where the product is well-defined by the ANDA in a manner that directly addresses the issue of infringement, the inquiry is "grounded" in the ANDA. Elan, 212 F.3d at 1248.

first two factors, i.e., likelihood of success on the merits and irreparable harm." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). Because Tyco has failed to show that it is likely to succeed on the merits, and thus failed to establish one of the two essential factors, this Court need not reach the other factors in the preliminary injunction analysis.

II. Mutual's motion for judgment on partial findings

At the conclusion of the presentation of evidence at the hearing, Mutual moved for judgment of noninfringement on partial findings, pursuant to Federal Rule of Civil Procedure 52(c), which states:

> If a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

This Court considers this motion in regard to the issue of noninfringement of claim 2 pursuant to 35 U.S.C. § 271(e)(2)(A). At the hearing, this Court asked Tyco whether there was anything it had not presented in regard to the question of infringement under Elan, and Tyco answered in the negative. This Court concludes that Tyco has been fully heard on the issue of noninfringement pursuant to 35 U.S.C. § 271(e)(2)(A). For the reasons explained supra, this Court grants the motion for judgment on partial findings. Judgment of noninfringement of claim 2, pursuant to 35 U.S.C. § 271(e)(2)(A), will be entered in favor of Mutual. This does not constitute a judgment of noninfringement under 35 U.S.C. § 271(a).

Pursuant to FED. R. CIV. P. 52(a), the Court presents its findings of fact and conclusions of law.

FINDINGS OF FACT

I. The parties stipulated to the following undisputed facts:

1. Tyco owns U.S. Patent No. 5,211,954.

2. On November 1, 2006, Mutual filed ANDA No. 78-581 with the FDA, seeking to sell a generic 7.5 mg temazepam product before the expiration of the '954 patent.

3. The 30-month stay of FDA approval of ANDA No. 78-581 expires on August 12, 2009.

4. Mutual intends to market a generic 7.5 mg temazepam product upon expiration of the 30-month stay and final FDA approval of ANDA No. 78-581.

II. Based on the evidence presented at the preliminary injunction hearing, this Court now makes the following findings of fact:

1. ANDA No. 78-851 specifies that the SSA of the proposed temazepam product is at least 2.2 square meters per gram.

2. Mutual has not received final FDA approval of ANDA No. 78-851.

CONCLUSIONS OF LAW

1. Claim 2 of the '954 Patent is limited to temazepam with a specific surface area in the range of 0.65 to 1.1 square meters per gram.

2. ANDA No. 78-851 defines the proposed temazepam product in a manner that directly addresses the issue of infringement. A product manufactured to the ANDA's specifications could not literally infringe the '954 Patent.

3. The product that Mutual, the applicant in ANDA No. 78-851, will likely market if its application is approved has a specific surface area that does not infringe claim 2 of the '954 Patent.

4. Mutual's motion for entry of judgment of noninfringement on partial findings, pursuant to Federal Rule of Civil Procedure 52(c), is **GRANTED**.

5. As to Tyco's claim of infringement of claim 2 of U.S. Patent No. 5,211,954, pursuant to 35 U.S.C. § 271(e)(2)(A), judgment of noninfringement is entered in

favor of Mutual.

6. Given the judgment of noninfringement, Tyco cannot succeed on the merits in proving its claim of infringement of claim 2 of U.S. Patent No. 5,211,954, pursuant to 35 U.S.C. § 271(e)(2)(A).

7. Absent a demonstration of a likelihood of success on the merits, a preliminary injunction cannot issue.

8. The motion for a preliminary injunction is **DENIED**.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: August 4, 2009